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**Date:** 19.01.2012

**GAIN Report Number:** RS1204

## Russian Federation

**Post:** Moscow

### Regulatory Impact Assessment of Existing Amendment to Sanitary Norms

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

**Approved By:**

Morgan Haas

**Prepared By:**

Staff

**Report Highlights:**

Russia's Ministry of Economic Development (MED) invites all interested parties to comment on the 22<sup>nd</sup> Amendment to the Russian Sanitary Norms on Food Products (SanPiN 2.3.2.1078-01) in order to assess the regulatory impact of the document. Comments should be submitted by February 15, 2012. Among other things, this is an opportunity to bring any of the Amendment's inconsistencies with international standards to the attention of the Russian Government.

**General Information:**

Russia's Ministry of Economic Development (MED) invites all interested parties to comment on the 22<sup>nd</sup> Amendment to the Russian Sanitary Norms on Food Products (SanPiN 2.3.2.1078-01) in order to assess the regulatory impact of the document. Comments should be submitted according to a specified MED [form](#) by February 15, 2012. Among other things, this is an opportunity to bring any of the Amendment's inconsistencies with international standards to the attention of the Russian Government.

Interested U.S. parties are encouraged to forward their comments and concerns in Russian directly to MED's Department for Assessment of Regulatory Impact at [SubbotinaMM@economy.gov.ru](mailto:SubbotinaMM@economy.gov.ru). Please also consider copying FAS/Moscow at [AgMoscow@fas.usda.gov](mailto:AgMoscow@fas.usda.gov) on your comments in order for them to be considered as part of the official U.S. Government comments to the Russian Government. FAS/Moscow can also assist you in translation if you provide your comments to us one week before the end of the comment period.

For English translation and information about the 22<sup>nd</sup> Amendment to the Russian Sanitary Norms on Food Products (SanPiN 2.3.2.1078-01) please see GAIN Report RS1116 of March 31, 2011 "[Amendment to Sanitary Norms Establishes Several New MRLs](#)." The Amendment came into force on April 8, 2011. While the Ministry of Health and Social Development (MoHSD) suspended the Amendment by its order N1526 of December 12, 2011, the current legal status of both MoHSD order N1526 and the 22<sup>nd</sup> Amendment is not clear at this point.

An unofficial translation of the MED notice inviting public comments on the document and MED form with specific questions to address in the comments follows.

**By herewith the Ministry of Economic Development of the Russian Federation notifies about holding public consultations for expert review of a regulatory legal act**

**Regulatory act:**

Resolution of the Chief State Sanitary Doctor of the Russian Federation No. 177 of December 27, 2010 «On Approval of SanPiN 2.3.2.2804-10 «Additions and amendments No. 22 to SanPiN 2.3.2.1078-01 «Hygienic Requirements to Safety and Nutritional Value of Food Products»

**Developer of the draft act:**

*Rospotrebnadzor*

**Public consultations period:**

January 16, 2012 – February 15, 2012.

**Method of forwarding responses:**

Forwarding electronically to the following e-mail: [SubbotinaMM@economy.gov.ru](mailto:SubbotinaMM@economy.gov.ru) as attached file, prepared (filled out) according to the attached form, including in the Word format.

**Contact person for questions on filling out the form and its forwarding:**

Department for Assessment of Regulatory Impact of Russia's Ministry of Economic Development, Mariya Mikhailovna Subbotina, phone: +7 (495) 697 08 77, from 9-30 am to 5-00 pm on work days.

**Documents attached to the request:**

Resolution of the Chief State Sanitary Doctor of the Russian Federation No. 177 of December 27, 2010 «On Approval of SanPiN 2.3.2.2804-10 «Additions and amendments No. 22 to SanPiN 2.3.2.1078-01 «Hygienic Requirements to Safety and Nutritional Value of Food Products»

**Responsible divisions of Russia's Ministry of Economic Development:**

Department for Assessment of Regulatory Impact.

**Comment**

The present expert review is carried out in accordance with Decree of the Government of the Russian Federation No. 633 of July 19, 2011 «On Expert Review of Regulatory Legal Acts of the Federal Executive Bodies for the Purpose of Detecting Provisions therein, which Unreasonably Hamper Entrepreneurial and Investment Activity, and on Amending Some Acts of the Government of the Russian Federation».

The regulatory act approves the Rules for organizing work on the issuance of veterinary documents, which are mandatory for officials authorized to process and issue veterinary documents, legal persons of any form of incorporation and citizens involved in the care, catch, and harvesting of animals (including birds, fish (other hydrobionts), and bees), as well as in the production, procurement, processing, transportation, storage, and sales of products of animal origin, feeds, and feed additives.

The Ministry of Economic Development is holding public consultations for the purpose of an expert review of the act and detection of provisions therein, which impose excessive administrative and other restrictions and responsibilities on performers of entrepreneurial or other activities, as well as provisions conducive to imposing unreasonable expenses on performers of entrepreneurial or other activities or budgets of all levels of the budget system of the Russian Federation. All interested persons are invited to forward their opinion on the attached issues in the framework of the mentioned consultations.

**LIST OF ISSUES TO BE ADDRESSED IN THE FRAMEWORK OF THE PUBLIC CONSULTATIONS FOR EXPERT REVIEW**

of the Resolution of the Chief State Sanitary Doctor of the Russian Federation No. 177 of December 27, 2010 «On Approval of SanPiN 2.3.2.2804-10 «Additions and amendments No. 22 to SanPiN 2.3.2.1078-01 «Hygienic Requirements to Safety and Nutritional Value of Food Products»

Please, fill in and forward this form to the following e-mail SubbotinaMM@economy.gov.ru no later than February 15, 2012.

Experts will not be able to analyze positions, forwarded to the Ministry of Economic Development, as well as forwarded in a different format than the attached form after the stated period.

### Contact Information

If you wish, please, indicate the following:

Name of the organization

Sphere of the organization's activity

Contact person's name

Contact phone

E-mail

1. Which issue was to be addressed by adoption of the regulatory legal act? Is this issue still relevant today?
2. Which behavioral reasons contribute to the emergence of the stated issue?
3. How well has the developer of the regulatory legal act identified the factors that determine the need for government intervention? How well does the objective of the government regulation correspond to the current problem situation?
4. Is the chosen option an optimal solution (including from the point of view of the social benefits and costs)? Are there other options for achieving the objectives of the government regulation, in particular please highlight those, which, in your opinion, would be less expensive (optimal) for entrepreneurial and investment activities?
5. Please name the major players subject to the government regulation?
6. Does the introduction of the government regulation influence the competitive environment in the industry? How will the competition change if the regulatory legal act is brought in line with your suggestions (after the amendments are introduced)? How will the competition change if the act is cancelled?
7. What costs are incurred by the performers of the entrepreneurial and investment activities in connection with the adoption of the regulatory legal act (emphasize: types of costs, their value, number of such transactions per year)? Which of the stated costs do you consider excessive?
8. Please evaluate how well and accurately the duties and responsibilities of the recipients of the government regulations, as well as administrative procedures, implemented by the authorized executive bodies are reflected in the regulatory legal act?
9. Is there a mechanism for economic entities to protect their rights and is a non-discriminatory treatment ensured by the implementation of the provisions of the regulatory legal act?
10. Which provisions of the regulatory legal act unreasonably hamper entrepreneurial and investment activities? Please provide justification for each of the specified provisions and in addition please determine the following:

*If the specified provision is in a semantic contradiction with the purposes of the regulation or the existing issue; or if it does not contribute to the achievement of the regulatory goals;*

*If it is of a technical error's nature (introduced ambiguity or contradiction);*

*If it leads to redundant action, or, on the contrary, constrains the actions of the performers of the entrepreneurial and investment activities;*

*If it creates considerable risks for conducting entrepreneurial or investment activities, contributes to the emergence of unreasonable rights of the government bodies or other officials or permits selective application of the rules;*

*If it makes it impossible for entrepreneurs or investors to perform legal actions (for example, in connection with the absence of infrastructure, organizational or technical environment, or technologies) or if it does not establish the operating procedure in the best possible way;*

*If it contributes to an unjustified change in the alignment of forces in an industry;*

*If it does not correspond to the customary business practice in the industry or does not comply with current international practices;*

*If it does not conform to the applicable legislation.*

*11. Please make suggestions on each of the provisions that you specified as unreasonably hampering the activities. If possible, please suggest alternative ways to solve the issue, identifying the best among them.*

*12. Please evaluate your suggestions from the point of view of their impact on other participants – how will relations and risks change?*

*13. How will the costs change for each of the social relation groups (entrepreneurs, state, society) – identifying the recipients of the regulation among them, if your proposals for amendments/cancellation are accepted? If possible, please provide a risk assessment in monetary terms (by type of operations and number of transactions per year).*

*14. If you have any additional remarks, comments, and suggestions on the present act, you can identify them in any form:*

*Or in the form of the following table:*

The Provision of the Act	Comments	Suggestions